General

Guideline Title

Traumatic brain injury medical treatment guidelines.

Bibliographic Source(s)

Colorado Division of Workers' Compensation. Traumatic brain injury medical treatment guidelines. Denver (CO): Colorado Division of Workers' Compensation; 2012 Nov 26. 119 p.

Guideline Status

This is the current release of the guideline.

Regulatory Alert

FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- December 14, 2016 – General anesthetic and sedation drugs: The U.S. Food and Drug Administration (FDA) is warning that repeated or lengthy use of general anesthetic and sedation drugs during surgeries or procedures in children younger than 3 years or in pregnant women during their third trimester may affect the development of children's brains. Consistent with animal studies, recent human studies suggest that a single, relatively short exposure to general anesthetic and sedation drugs in infants or toddlers is unlikely to have negative effects on behavior or learning. However, further research is needed to fully characterize how early life anesthetic exposure affects children's brain development.
- August 31, 2016 – Opioid pain and cough medicines combined with benzodiazepines: A U.S. Food and Drug Administration (FDA) review has found that the growing combined used of opioid medicines with benzodiazepines or other drugs that depress the central nervous system (CNS) has resulted in serious side effects, including slowed or difficult breathing and deaths. FDA is adding Boxed Warnings to the drug labeling of prescription opioid pain and prescription opioid cough medicines and benzodiazepines.
- May 10, 2016 – Olanzapine: The U.S. Food and Drug Administration (FDA) is warning that the antipsychotic medicine olanzapine can cause a rare but serious skin reaction that can progress to affect other parts of the body. FDA is adding a new warning to the drug labels for all olanzapine-containing products that describes this severe condition known as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).
- March 22, 2016 – Opioid pain medicines: The U.S. Food and Drug Administration (FDA) is warning about several safety issues with the entire class of opioid pain medicines. These safety risks are potentially harmful interactions with numerous other medications, problems with the adrenal glands, and decreased sex hormone levels. They are requiring changes to the labels of all opioid drugs to warn about these risks.

Recommendations

Major Recommendations

Note from the National Guideline Clearinghouse (NGC): This summary includes the treatment recommendations of the guideline. See the original guideline document for additional information on initial evaluation, diagnostic, and maintenance procedures for patients with traumatic brain injuries and for further descriptions of the therapies discussed below.

Acute Therapeutic Procedures—Non-operative

Resuscitation

The first priority in traumatic brain injury (TBI) is complete and rapid physiologic resuscitation.

Special considerations for isolated communities without neurosurgical support:

- Trauma surgeons and emergency physicians may perform the initial resuscitation and neurologic treatment in the deteriorating individual.
- Once the individual is stable, transport to a designated neuro-trauma center for further evaluation and management should occur expeditiously.

Intracranial Pressure (ICP) and Cerebral Perfusion Pressure (CPP)

ICP monitoring is indicated in individuals with a low Glasgow Coma Scale (GCS) (less than nine) or when the individual cannot have continual neurologic evaluation (e.g., use of anesthesia, pain medicine for other injuries that preclude a neurologic exam), and it should also be considered when the individual's age is over 40 or systolic blood pressure is less than 90 mmHg. ICP monitoring may be done by a variety of technologies, but a ventriculostomy is the most accurate. Other options include parenchymal monitors placed in the supratentorial cranial vault.

Cerebral oxygen saturation monitoring may be used, usually in conjunction with ICP monitoring, to assess the effects of treatment interventions on oxygen delivery to the injured brain, and to optimize the management of brain swelling and intracranial pressure in the setting of severe TBI.

Hyperventilation

Hyperventilation is generally not recommended in the setting of acute TBI. In rare cases, controlled hyperventilation may be necessary for brief periods in acute neurological deterioration not attributable to systemic pathology (i.e., hypotension), but it is not recommended for prolonged periods of time.

Medications

Hyperosmolar agents may be used prior to ICP monitoring if there is neurologic deterioration not attributable to systemic pathology (i.e., hypotension) and/or signs of transtentorial herniation.

Glucocorticoids (steroids) are not useful or generally accepted to improve outcome or decrease ICP, and in some instances may be harmful. There is good evidence that they do not decrease mortality, and there is some evidence that they may even increase the mortality rate in individuals with TBIs.

Anticonvulsants

- Anticonvulsant treatment may be used to prevent early post-traumatic seizures in the high-risk individual and are usually administered for one week in those with intracranial hemorrhage. Prevention of early seizures has no statistically significant impact on long-term outcome or the development of late seizures or chronic epilepsy. Prevention of early seizures is reasonable to reduce seizure-associated complications during acute management.
- Prophylactic anticonvulsants should not be used routinely after the first week unless other clinical indicators warrant their use, such as brain penetration, excessive intraparenchymal bleeding, or others.

Progesterone

- There is good evidence that progesterone in the setting of acute TBI can reduce mortality and disability, although most patients with severe TBI may not avoid residual disability, and the studies do not yet support routine use. Ongoing studies may change this recommendation.

Hypothermia

Therapeutic hypothermia involves the lowering of core body temperature by such techniques as surface heat exchange devices, intravascular infusion of cold crystalloid, and body cavity lavage. This is done in order to decrease some metabolic and physiologic processes that result in neural damage after TBI, including increased ICP.

Because of the complexities of the determinants of outcome of hypothermia, recommendations cannot be made regarding its routine use. Decisions for or against its use must be made on a case-by-case basis according to factors of severity of injury, time since injury, level of ICP, the presence of other injuries, and other circumstances. Side effects include immunosuppression, cold diuresis with hypovolemia, electrolyte disturbances, impaired drug clearance, and mild coagulopathy.

In contrast to the appropriateness of induced hypothermia, there is general agreement that fever with the TBI patient is associated with poor long-term outcomes and should be monitored and managed.

Surgery

In many cases, surgery is appropriate (refer to the "Operative Therapeutic Procedures" section below for details).

Hyperbaric Oxygen

Despite evidence of limited physiological changes with hyperbaric oxygen, there is insufficient evidence to suggest that hyperbaric oxygen would functionally benefit stroke or TBI patients. Complications can occur, including tension pneumothorax. Hyperbaric oxygen is not recommended acutely or chronically. Ongoing studies could affect this recommendation.

Non-operative Therapeutic Procedures—Initial Treatment Considerations

Due to the complex nature of the brain, individuals with TBI require coordinated interdisciplinary treatment. Usually, the impairment(s) and functional limitations are appropriately treated by more than one therapeutic discipline. Treatment should emphasize functional, outcome-oriented, and community reintegration goals. Treatment session duration and frequency will vary depending on the individual's tolerance and may evolve over time. The location of treatment sessions may be in a clinical setting initially, but eventually may be more effective in the home, workplace, or community, based on functional goals. Moderate/severe TBI may result in lifetime deficits, so a long-term disability management model is appropriate. Frequency and duration of specific, non-acute treatments should be included in every treatment plan and should be re-evaluated approximately every four weeks (refer to Section B., "General Guideline Principles," in the original guideline document). Experienced practitioners should not use all of the therapies and modalities listed in this guideline. Periodic modification or consultation may be necessary throughout an individual's lifetime following TBI. Therapy for specific impairments and functional limitations may be reinitiated for goal-specific, time-limited treatment as new goals are identified and developed. Treatment should be based on medical diagnosis and associated impairment, cognitive ability, clinical evaluations, anticipated functional gains, and progress demonstrated by documented functional outcomes.

Patient/Family/Support System Education

Education for individuals with TBI and their family and/or support system is appropriate, generally accepted, and widely used in TBI rehabilitation.

Mild TBI (MTBI)

Most cases will progress to recovery with sufficient education and not require interdisciplinary treatment.

Moderate/severe TBI

Formal treatment team conferences involving the individual with TBI, family and/or support system individuals and case managers, including insurance case manager, should be held regularly during the inpatient, residential, neurobehavioral, and outpatient phases of rehabilitation and periodically during the home and community-based phases of community reintegration. Education may include, but may not be limited to, brain-behavior relationships, health issues related to TBI and co-morbid illnesses or injury, family and/or support system interventions, emotional adjustments, and family and/or support system roles changes. Families and/or support systems and individuals with TBI require education, support, and caregiver training as part of the long-term maintenance plan. Education for the individual and family and/or support system is typically provided by case managers, social workers, rehabilitation counselors, family counselors, licensed mental health professionals, and/or nurses.

Behavior

Moderate/severe TBI – Behavioral therapy is a well-accepted and widely used therapy for TBI; it acknowledges that behavioral problems are always multi-factorial and therefore should consider medical, neurosurgical, neurological, psychiatric, environmental, and psychosocial issues. Behaviorally based therapies rely on an interdisciplinary treatment team approach and are frequently implemented in conjunction with cognitive

and/or other psychological treatment. A behavioral therapy plan should be approved and monitored by a neuropsychologist, psychologist, behavior analyst, or physician familiar with TBI.

Cognition

There is some evidence that a cognitive program aimed at high order reasoning instruction is likely to improve some aspects of executive function (e.g., working memory, inhibition, switching tasks) for chronic TBI individuals. There is some evidence that intensive therapy, 15 hours/week for 16 weeks in a group setting emphasizing integration of cognitive, interpersonal, and functional gains, is superior to the same amount of therapy from multiple individual providers.

There is good evidence that structured, goal-oriented, individualized multidisciplinary cognitive rehabilitation for patients requiring hospitalization improves mobility, personal care, and independence in activities of daily living (ADLs) for individuals with TBI. Improvement in mobility and independence significantly reduces indirect costs over a long period of time, which may not be measured accurately in the relatively short periods during which most clinical studies are conducted. Cognitive rehabilitation is recommended by the Department of Veterans Affairs/Department of Defense (VA/DoD) for treatment of individuals with TBI with cognitive deficits.

MTBI

In MTBI, acute cognitive deficits are common, and spontaneous cognitive improvement is expected within the first three months, frequently within days or weeks, in the majority of injured individuals. There is good evidence that MTBI without post-traumatic amnesia does not routinely require multidisciplinary rehabilitation. There is some evidence that routine scheduling for cognitive rehabilitation for uncomplicated MTBI is not likely to improve outcomes and that MTBI cases with a psychiatric history are more likely to benefit from routine assessment for cognitive rehabilitation treatment. Compensatory memory strategies are useful in this population.

Rehabilitation of cognitive impairments should only be initiated if:

- The individual is not demonstrating the expected cognitive improvement.
- The individual exhibits more severe cognitive impairments on formal evaluation.
- The individual's vocation or other life circumstances necessitate the learning of compensatory strategies.
- There are safety issues in question (e.g., possible harm to self or others).

Moderate/Severe TBI

In individuals with moderate/severe TBI, rehabilitation of cognitive deficits is appropriate, clinically necessary, and based on evidence. Rehabilitation is most beneficial when an individual demonstrates adequate arousal, appropriate responsiveness to stimulation and at least a minimum ability to focus attention (e.g., fully oriented). Prior to demonstration of these skills, rehabilitation efforts should focus on monitoring and attempting to elicit responses, environmental structuring (e.g., maintaining a normal sleep/wake cycle), and staff/family and/or support system education.

Rehabilitation includes procedures designed to improve cognitive efficiency, develop specific cognitive skills, enhance awareness of impairments and skills, and develop appropriate compensation strategies for residual cognitive deficits. Individuals with MTBI and memory deficits are more likely to improve with compensatory memory strategies training than individuals with moderate/severe TBI who may require memory notebooks or other external aids to improve memory.

Computer-Based Treatment

The use of computers as a primary and independent form of treatment in cognitive remediation has limited application because of: (1) limitations in the rationale and specific application of software programs to address the needs of the individual with TBI and (2) difficulty with generalization of learned computer skills into functional environments. Integrated computer-based treatment (i.e., both individualized cognitive and interpersonal therapies) may improve functioning within the context of an interdisciplinary, neuropsychological rehabilitation program. Computer-based interventions that include active therapist involvement to foster insight into cognitive strengths and weaknesses, development of compensatory strategies, and facilitation of transferring skills into real-life situations may be used as part of a multi-modal intervention for cognitive deficits. Sole reliance on repeated exposure and practice on computer-based tasks without extensive involvement and intervention by a therapist is not recommended.

Assistive Technology

A variety of devices are available to assist individuals with language and functional problems. These should be trialed within a rehabilitation therapy program by physical therapists, occupational therapists and speech-language therapists, to determine which tools are most suitable for individual

cases.

Psychological/Educational Interventions

Psychological and educational interventions may include, or be performed in conjunction with, cognitive and behavioral treatment. Cognitive behavioral therapy (CBT) is a specialized goal-oriented systematic process used to problem solve that focuses on changing thought processes and is usually provided by a trained therapist or psychologist. One study noted sustained improvement after six months with either face-to-face or telephone contact. This should always be performed within the construct of a fuller therapy program.

When the degree of cognitive symptoms exceeds what would be expected given objective findings, the mechanism of injury, or acute signs of MTBI, or if there is an unexplained, marked worsening of cognitive symptoms over time, the possibility that the symptoms are psychological rather than neuropsychological in origin should be evaluated. A psychological evaluation is especially important if the injury occurred in an emotionally traumatic context, or if there are clinical indications of another mental health disorder.

Acute Psychological/Educational Interventions in MTBI

Early interventions that educate individuals, their family and/or support system, or the employer about the symptoms, natural history, prognosis, and management of MTBI symptoms are very important. Psychological interventions to educate the individual and family and/or support systems regarding coping may occur with the individual and family and/or support system, or alternatively with close friends and co-workers.

When certain risk factors are present, psychological interventions are appropriate to promote positive coping skills and to manage symptoms. Risk factors include the following: usual recovery does not occur, history of previous TBIs, the desire to return to a highly demanding job, significant injury stress, pre-injury psychiatric disorder, pre-injury learning disability, post-traumatic amnesia (PTA) greater than four to six hours, loss of consciousness greater than 10 minutes, chronic pain, substance abuse, poor psychosocial support, depression, or associated orthopedic injuries. The presence of other injuries requiring medical attention should not exclude anyone from appropriate psychological treatment. When licensed mental health professionals other than psychologists or psychiatrists are providing treatment, their therapy plan should be overseen by a psychologist, neuropsychologist, or psychiatrist.

Problem-Specific Referrals during the First Three Months following MTBI

Mental health services are appropriate to address specific problems that are directly caused by the injury (e.g., memory deficits, slowed speed of thinking, difficulties with decision making, irritability and fatigue) or that are secondary to the injury (e.g., anxiety, depression, adjustment disorder, difficulties with self-acceptance, and difficulties in adapting one's work demands to diminished cognitive capacity). PTSD may be present in a minority of MTBI patients and should be assessed early on and treated. Mental health interventions to address PTSD may include individual psychotherapy, cognitive/behavioral therapy, instructions in specific techniques such as relaxation training or biofeedback, instruction in symptom management, trauma resolution techniques (e.g., eye movement desensitization and reprocessing [EMDR]), group therapy, medications, and interventions in the community.

The interdisciplinary treatment team approach is particularly beneficial in these cases and it is strongly encouraged, especially during the first three months post-injury. Medications may be helpful to address the individual's symptoms (refer to the "Medications" section above).

Referrals Three or More Months Post-MTBI

A referral for psychological and/or psychiatric services should strongly be considered at three or more months post-injury when the individual is having difficulty coping with symptoms or stressors, or when secondary psychological symptoms such as intolerance to certain types of environmental stimuli or anxiety or depression are hindering recovery and return to pre-injury level of function.

Functional Gains

To be documented and achieved with therapy and may include, but are not limited to, improved mood, irritability, frustration tolerance, concentration, memory, sleep quality, and interpersonal skills such as empathy and capacity to effectively interact with family and/or support system members and co-workers.

Psychological Interventions–Moderate/Severe TBI

Moderate/severe TBI may result in a variety of cognitive, psychological and/or behavioral symptoms which, if left untreated, can negatively impact each other, recovery from TBI, and/or functional outcomes; therefore, psychological treatment is recommended for patients with any of these symptoms. Psychological interventions may include, or be performed in conjunction with, cognitive and behavioral treatment. Although the effect of this treatment for the brain injured population is unknown, psychological treatment is recommended for all patients with psychological symptoms. Refer to the original guideline document for specific recommendations for the (1) acutely symptomatic phase, (2) early recovery phase, and (3)

stabilization phase.

Consultation in Regard to Usage of Medications

Medication management for emotional, behavioral, cognitive and physical functioning, for moderate/severe TBI patients is often needed. An interdisciplinary team approach is beneficial and encouraged. Thus, attending physicians will often request consultation from other physicians, including psychiatrists, and non-physician team members, such as psychologists, social workers, and family service counselors, to provide data and input regarding behavioral observations that may assist in assessing how the person is responding to various medications.

Medication/Pharmacological Rehabilitation

The use of medications requires careful monitoring and collaboration between the individual, physician, family and/or support system, and other members of the interdisciplinary team. Common symptom categories targeted for medication treatment may include, but are not limited to:

- Pain (headache, axial, soft tissue, etc.) (refer to the "Headache" section below)
- Sensory alterations (dysesthesias)
- Motor symptoms (motor control, coordination, spasticity, weakness, Parkinsonism, tremor, etc.)
- Emotional conditions (depression, lability, anxiety, etc.)
- Behavioral problems (poor self-monitoring, dyscontrol, irritability, aggression, poor initiation, etc.)
- Cognitive issues (arousal, attention, speed of processing, memory, executive function, fatigue)
- Psychotic symptoms (disturbances of thought content such as hallucinations and delusions, thought process, and thought disorganization, which can contribute to behavioral problems)
- Neurological issues (seizures, paroxysmal sympathetic hyperactivity, etc.)
- Disturbances of sleep (insomnia, hypersomnia, sleep-wake cycle reversals)
- Endocrine dysfunction

There is no single formula for pharmacological treatment of patients with acute, subacute, or chronic problems due to TBI of any level of severity. A thorough medication history, including use of alternative and over-the-counter medications, should be performed initially and when medication changes are made. The medication history may consist of gathering corroborating information from caregivers and prescribing pharmacies, particularly if the individual has memory or other deficits which may impair their ability to accurately report their medications and adherence to the prescriber. Appropriate application of pharmacological agents depends on the patient's age, past history (including history of substance abuse), drug allergies, and all medical problems. It is incumbent upon the healthcare provider to thoroughly understand pharmacological principles when dealing with the different drug classes, their respective side effects, drug interactions, bioavailability profiles, and the primary reason for each medication's usage. Patients and their caretakers should be aware that medications alone are unlikely to provide complete symptom relief. A primary goal of drug treatment is to improve the patient's function as measured behaviorally. Essential elements of post-traumatic deficits require continuing participation in rehabilitative programs appropriate to and consistent with the level of recovery and techniques such as cognitive behavioral therapy and other individualized physical and psychological practices, as described elsewhere in this guideline.

Control of chronic post-traumatic deficits, particularly in moderate/severe TBI, is expected to involve the use of medication. Strategies for pharmacological control of post-traumatic symptoms cannot be precisely specified in advance. Rather, drug treatment requires close monitoring of the patient's response to therapy, flexibility on the part of the prescriber, and a willingness to change treatment when circumstances change; this includes lowering and/or discontinuing medications when symptoms improve and periodic trials of lowering medications when symptoms are stable. Many of the drugs discussed in the medication section are Food and Drug Administration (FDA)-approved for other indications but may appropriately be used for various aspects of TBI treatment and associated conditions. When prescribing off-label FDA use of a medication, indications and goals should be clearly stated as part of a comprehensive, functionally based treatment plan. It is generally wise to begin management with lower cost medications whose safety and efficacy equals that of higher cost medications, and medications with a greater safety profile. Decisions to progress to more expensive, non-generic, and/or riskier medications are made based on the drug profile, patient/caregiver feedback, and improvement in function. The provider should carefully balance the untoward side effects of the different drugs with therapeutic benefits, as well as monitoring for any drug interactions.

Prescribed medications should be given an appropriate trial in order to test for therapeutic effect and tolerance to the medication. The length of an appropriate trial varies widely depending on the drug, as well as the individual and their response to the drug. Certain medications may take several weeks to months (e.g., antidepressants) to determine the efficacy, while others require only a few doses (e.g., psychostimulants). It is recommended that patients with chronic post-TBI symptoms who require maintenance medications use those that have the least serious side effects.

Drugs of potential abuse, such as sedative/hypnotics or benzodiazepines, should be used sparingly in properly selected patients, e.g., for refractory insomnia, although total elimination of these medications is desirable whenever clinically feasible. It is strongly recommended that such

pharmacological management be monitored or managed by an experienced physician, and referral to a specialist experienced in TBI may be necessary. Non-pharmacologic interventions should be used in combination with pharmacologic treatments to minimize the amount of medication necessary in patients with all levels of severity of TBI. Clinical pharmacologist can provide useful guidance in medication selection.

Problems associated with mild, moderate, and severe TBI can be treated with a variety of medications; however, all have specific side effects and interactions of which clinicians should be mindful. Persons who sustain a TBI, particularly moderate/severe TBI, are particularly sensitive to central nervous system side effects, such as sedation, dizziness, cognitive impairment, and motor impairment. Starting doses and titration of medications will usually need to start lower and go slower, respectively; target doses may also be lower than when using these medications in a person without a TBI. MTBI cases are less likely to require medication as the majority of cases do well without prescription medications. When medication is used for MTBI, it is reasonable to consider a trial of tapering at one to two years post-injury.

For the clinician to interpret the following material, it should be noted that: (1) drug profiles listed are not complete; (2) dosing of drugs will depend upon the specific drug, especially for off-label use; (3) not all drugs within each class are listed, and (4) other drugs within the class may be appropriate for individual cases. Clinicians should refer to informational texts or consult a pharmacist before prescribing unfamiliar medications or when there is a concern for drug interactions.

The following drug classes are listed in alphabetical order, not in order of suggested use.

Affective Disorders Medications

Classified into a number of categories based on their chemical structure and their effects on neurotransmitter systems. Their effects on depression are attributed to their actions on norepinephrine, serotonin, and dopamine at the level of the synapse; although these synaptic actions are immediate, the symptomatic response in depression is delayed by several weeks. Selective serotonin reuptake inhibitors (SSRI) or serotonin-norepinephrine reuptake inhibitors (SNRI) may be used first line, although there is more data to support the use of SSRIs as first line intervention. Doses should be started low and slowly increased with attention to any fatigue, headache, insomnia, or drowsiness, which could impede cognitive progress. Several sources recommend citalopram or sertraline as they may also have a dopaminergic effect. These drugs have fewer drug interactions and are likely better tolerated. Tricyclic antidepressants (TCA) may also be used, however some have sedating qualities. A combination of dextromethorphan and quinidine may be used for patients suffering from pseudobulbar affect, which manifests as frequent, involuntary, and sudden episodes of crying or laughing. This can be seen in TBI and should be distinguished from depression and mania/hypomania to assure that the correct medication is used. There is no generic brand of this medication at the time of this guideline.

Behavior/Aggression Medications

There are no FDA-approved drugs for the treatment of aggression in TBI, but many agents have been shown to possibly have efficacy, including antipsychotics, antidepressants, mood stabilizers, anticonvulsants, and beta blockers. Beta blockers are relatively contraindicated in patients with asthma, heat block, or diabetes. Although there is some data suggesting that conventional and atypical antipsychotics can slow recovery from TBI, they may assist in the management of highly agitated or psychotic patients and those patients with co-morbid mood disorders. Use of these drugs should include careful monitoring for the development of tardive dyskinesia, weight gain, impaired cognition or coordination, hyperlipidemia, and glucose intolerance. An attempt to periodically reduce the dose or completely eliminate the drug should be made once the patient has stabilized, and clinicians should have a low threshold for consulting a psychiatrist if prolonged use of the class of medication appears likely. All medication use should consider the effects on cognition and interaction with other medication. Anti-epileptic medications, such as carbamazepine and valproate and other antihypertensive medications, such as clonidine, may also be beneficial.

Cognitive Enhancers

Several areas are addressed by these agents: memory, attention, speed of information processing, executive function, and other general cognitive domains. Many of the medications are off-label use, and all should be carefully followed for side effects that may interfere with recovery. Medications given to improve cognition should be monitored with periodic neuropsychological assessment or cognitive screening to confirm positive response and the need to continue the medication. These medications should also have trial decreases periodically for eventual weaning. Most cognitive enhancers fall into the general categories of stimulants, cholinesterase inhibitors, or dopamine enhancers. The VA/DoD and other studies support the use of methylphenidate, modafinil, or amantadine in some cases with impaired cognitive function.

Moderate/severe TBI cases will require individual management due to the number of issues being addressed, cognitive changes over time, and drug interactions. Considering these issues and the limited number of adequate studies in this area, with many published articles having small case sizes or non-randomized controls, medication regimes for moderate/severe TBI patients have wide variation.

The alphabetical list following is neither exhaustive nor complete regarding side effects, drug interactions, or studies not included in this review. Providers are advised to seek other sources for detailed drug prescribing information.

Please refer to the original guideline document for descriptions, indications, contraindications, dosing, time to therapeutic effect, major side effects, and drug interactions for the following medications:

- Amantadine
- Bromocriptine
- Carbidopa/L-dopa
- Dextroamphetamine and mixed amphetamine salts
- Donepezil
- Methylphenidate
- Modafinil and armodafinil
- Rivastigmine
- Other medications approved for use in Parkinson's

Hypnotics and Sedatives

Sedative and hypnotic drugs generally decrease activity and induce drowsiness, although some patients may experience agitation with use. Many drugs produce these effects incidental to their usual intended effects, similar to the side effects of many antihistamines and antidepressants. Due to the habit forming potential and adverse cognitive side effects of the benzodiazepines and other drugs found in this class, they are not routinely recommended but may be useful temporarily in some patients with sleep disturbances. Benzodiazepines may be indicated to treat alcohol withdrawal in TBI, but their use in the acute post-injury period after TBI is otherwise discouraged. Most insomnia in TBI patients should be managed primarily through environmental and behavioral interventions, including cognitive behavioral therapy, with medications as secondary measures (refer to the "Disturbances of Sleep" section below).

Non-steroidal Anti-inflammatory Drugs (NSAIDs)

NSAIDs are useful for pain and inflammation. In mild cases, they may be the only drugs required for analgesia. There are several classes of NSAIDs, and the response of the individual injured worker to a specific medication is unpredictable. For this reason, a range of NSAIDs may be tried in each case with the most effective preparation being continued. Patients should be closely monitored for adverse reactions. The FDA advises that all NSAIDs may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. There is good evidence that naproxen has less risk for cardiovascular events when compared to other NSAIDs. Administration of proton pump inhibitors (PPI), histamine 2 (H2) blockers, or prostaglandin analog misoprostol along with these NSAIDs may reduce the risk of duodenal and gastric ulceration but do not impact possible cardiovascular complications. Due to the cross-reactivity between aspirin and NSAIDs, NSAIDs should not be used in aspirin-sensitive patients, and they should be used with caution in all asthma patients. NSAIDs are associated with abnormal renal function, including renal failure, as well as abnormal liver function. Certain NSAIDs may have interactions with various other medications. Individuals may have adverse events not listed above. Intervals for metabolic screening are dependent on the patient's age and general health status and should be within parameters listed for each specific medication. Complete blood count (CBC), liver function, and renal function should be monitored at least every six months in patients on chronic NSAIDs and initially when indicated.

See the original guideline document for additional discussion of NSAIDs and selective cyclo-oxygenase-2 (COX-2) inhibitors.

Skeletal Muscle Relaxants

Most useful for acute musculoskeletal injury or exacerbation of injury. Chronic use of benzodiazepines is discouraged due to their habit-forming potential, negative effects on cognition, and seizure risk following abrupt withdrawal. Carisoprodol should not be used because the opioid meprobamate is a metabolite.

Opioids

Headache

Headache is one of the most common symptoms seen in general medical practices. Following TBI, 50% or more of injured individuals experience headache. The majority of these are self-limited, but headache persisting for more than three months may occur. Brain damage is unlikely to be responsible for post-traumatic headache, which is seen more commonly after MTBI than after moderate/severe TBI. Rather, involvement of extracranial structures, such as the temporomandibular joint (TMJ), the sinuses, and the muscles attaching to the occiput accounts for most headaches following TBI (refer to the Division's Cervical Spine Guidelines when appropriate).

Headaches may persist longer when associated with other symptoms such as dizziness, memory problems or weakness. Therefore, every effort should be made to identify the cause and treat headaches and other symptoms as early as possible.

Refer to the Headache Treatment Algorithm in the original guideline document for preventive and abortive pharmacological treatments as well as nonpharmacological treatment options.

Long-term maintenance plans are necessary in chronic headache management. Medications may be necessary for an indefinite period; however, a distinction should be made between headache conditions that were pre-existing and those caused by the TBI. In MTBI, most cases will not result in debilitating frequent headaches. If the patient is suffering from debilitating headaches, a full review of the diagnosis, triggering events, and psychosocial issues should take place. All headache treatment modalities should be independent and functional. Even if headaches are permanent, it is expected that the individual will be functional and able to return to work.

Botulinum Injections

Botulinum injections are no longer generally recommended for cervicogenic or other headaches based on good evidence of lack of effect. Botox may be considered in a very small subset of patients with chronic migraines 12 to 15 days/month who have failed all other conservative treatment, including trials of at least three drug classes, and who have committed to any life style changes related to headache triggers.

Therapeutic Exercise

With or without mechanical assistance or resistance, therapeutic exercise may include isoinertial, isotonic, isometric, and isokinetic types of exercises as part of the overall occupational therapy physical therapy program, not to be used in isolation.

Indications include the need for cardiovascular fitness, improved muscle strength, improved connective tissue strength and integrity, increased bone density, promotion of circulation to enhance soft tissue healing, improvement of muscle recruitment, improved proprioception and coordination, and increased range of motion (ROM).

Patients and/or caregivers should be instructed in and receive a home exercise program that is progressed as their functional status improves. Upon discharge, the patient and/or caregiver would be independent in the performance of the home exercise program and would have been educated in the importance of continuing such a program. Educational goals would be to maintain or further improve function and to minimize the risk for aggravation of symptoms in the future.

Disturbances of Sleep

Sleep disturbances are common in all types of TBI. Objective sleep studies show reduced sleep efficiency, increased sleep onset latency, and increased time awake after sleep onset. These changes are associated with patient reports of non-restorative sleep. Sleep disorders can aggravate neurologic injury. Sleep apnea may be associated with endocrine disturbance arising from TBI and neuroendocrine assessment is highly recommended. Sleep apneas and other sleep disorders should be treated to optimize recovery from TBI.

Many patients develop behavioral habits that exacerbate and maintain sleep disturbances. Excessive time in bed, irregular sleep routine, napping, low activity, and worrying in bed are all maladaptive responses that can arise in the absence of any psychopathology. Behavioral modifications are easily implemented and can include:

- Maintaining a regular sleep schedule, including retiring and rising at approximately the same time on weekdays and weekends
- Avoiding daytime napping
- Avoiding caffeinated beverages after lunchtime
- Making the bedroom quiet and comfortable, eliminating disruptive lights, sounds, television sets, and keeping a bedroom temperature of about 65°F
- Avoiding alcohol or nicotine within two hours of bedtime
- Avoiding large meals within two hours of bedtime
- Exercising vigorously during the day, but not within two hours of bedtime, since this may raise core temperature and activate the nervous system
- Associating the bed with sleep and sexual activity only, using other parts of the home for television, reading, and talking on the telephone
- Leaving the bedroom when unable to sleep for more than 20 minutes and returning to the bedroom when ready to sleep again

These modifications should be undertaken before sleeping medication is prescribed for long term use. Modafinil, melatonin, and light therapy may be helpful for some patients.

<u>Non-operative Therapeutic Procedures—Neuromedical Conditions in Moderate/Severe Brain Injury</u>

There are a number of associated neuromedical problems unique to moderate/severe TBI. These conditions often require specialized evaluation and therapeutic interventions by physicians, nurses, and relevant interdisciplinary team disciplines. The resultant problems may be classified as

follows:

Neurological Complications

Ongoing evaluation is often necessary to detect the delayed development of space occupying intraparenchymal lesions, pneumocephalus, hydrocephalus, extra-axial lesions such as subdural and epidural hematomas, and hygromas. If an individual's neurological status worsens or plateaus, neuroimaging studies may be warranted.

Post-traumatic Seizures/Post-traumatic Epilepsy (PTE)

Major risk factors for the development of PTE include penetrating head wounds, hematoma, depressed skull fracture, and early seizures. The issue of seizure prophylaxis remains controversial in high-risk individuals. The role of routine seizure prophylaxis utilizing antiepileptic drugs (AED) is recommended for seven to ten days post-brain trauma. Prophylactic anticonvulsants should not routinely be used after the first week but at times may be appropriate for individual cases. The management of late post-traumatic seizures conforms to the treatment of "epilepsy." This includes principles of monotherapy, and compliance, considerations of cognitive, behavioral, emotional, and psychosocial functioning. Pseudoseizures should be treated by psychological and psychiatric therapy.

Cardiopulmonary Complications

Cardiac System

Hypertension in TBI is associated with tachycardia and increased cardiac output with normal or decreased peripheral vascular resistance. This is different from essential hypertension in which there is normal cardiac output with increased peripheral vascular resistance. The preferred treatment for this type of hypertension from hyperadrenergic activity is a beta adrenergic blocking agent or alpha-2 central agonist. However, these approaches should carefully consider the potentially negative cognitive, behavioral, and/or emotional side effects of those medications.

Pulmonary System

Moderate/severe TBI and related trauma to the chest wall may adversely affect respiratory function by compromising respiratory drive, swallow reflex, and cough. The main principle of therapeutic intervention is the avoidance of respiratory failure with appropriate oxygenation, ventilation, and airway control. Treatments may include mechanical ventilation, tracheostomy, routine swallow evaluation to evaluate for aspiration risk, and aggressive pulmonary hygiene.

Sleep Complications

Sleep disturbance is a relatively common complication following moderate/severe TBI. Depending on etiology, management strategies include, but are not limited to, sleep hygiene education, implementation of sleep hygiene, maintaining a normal day/night and wake/sleep cycle, limitation of time in bed and naps, surgery, various medical devices (e.g., oral appliance, continuous positive airway pressure), and medication therapy. Also refer to the "Disturbances of Sleep" section above.

Musculoskeletal Complications

Long-bone Fractures

When long-bone fractures occur in individuals with a TBI, aggressive, early surgical treatment is recommended within 2 to 12 hours after injury, provided that hemodynamic stability has been achieved. This would include open reduction and internal fixation, although the specific optimal technique has not been well-documented.

Heterotopic Ossification (HO)

Defined as the development of new bone formation in soft tissue planes surrounding neurologically affected joints, especially the hips, elbows, shoulder and knees, in order of common concurrence. Observation by nurses and physical therapists is essential and may include documentation of decreased ROM, joint inflammation, pain, and/or a low-grade fever. Appropriate work-up may include laboratory studies revealing an elevated sedimentation rate and/or alkaline phosphatase with a normal CBC. Plain x-rays are necessary and appropriate; however, the most sensitive radiological study includes the three-phase bone scan and/or gallium scan, magnetic resonance imaging (MRI), and color Doppler ultrasound. These may be necessary in both the initial diagnostic and follow-up phases to guide treatment. Optimal treatment outcome involves early diagnosis, ROM exercise, and the use of disodium etidronate, which prevents mineralization. Other treatment options include NSAIDs, radiation, and surgery in the chronic state.

Gastrointestinal Complications

Individuals with moderate/severe TBI have demonstrated delays in gastric emptying with frequent regurgitation of nasogastric administered feedings. This, accompanied with dysphagia and/or an inadequate swallow reflex, places the individual at risk for aspiration pneumonia. Dysphagic individuals and those at risk may require total parenteral nutrition (TPN), gastric and/or post-pyloric feeding techniques. Either an endoscopically placed percutaneous endoscopic gastrostomy (PEG) or surgically placed gastrostomy and/or jejunostomy may be necessary for adequate ongoing nutritional support. Individuals with gastrointestinal hypomotility may require medications. Also, erosive gastritis may be a frequent complication, and the use of H2 blockers, PPIs, and antacid treatments are usually efficacious. Individuals with TBI may also be at risk for neurogenic bowel, which includes constipation, impactions, bowel obstructions, and/or loose stools. A nursing care regimen on a routine and then consultative basis, may be necessary to establish routine bowel programs.

Genitourinary Complications

Moderate/severe TBI may involve cerebral structures controlling bladder storage and emptying functions. This may result in a neurogenic bladder. Treatment of a neurogenic bladder is aimed at adequate emptying, prevention and treatment of infection, preservation of upper renal tract function, and avoidance of skin soiling from incontinence. An indwelling urethral catheter is often appropriate in the early stages of recovery. Once the urethral catheter is discontinued, either a condom catheter or diaper/adult brief is used for incontinence.

Following assessment of bladder emptying utilizing ultrasonography for post-void residual checks and urodynamic studies, decisions may be made regarding longer-term management strategies. This may include intermittent catheterization or rehabilitative bladder training utilizing anticholinergic medications and time-interval voiding techniques. Urological consultation and more comprehensive diagnostic studies that may include, but are not limited to, cystoscopy, urodynamics, and renal functions studies may also be necessary. Sexual dysfunction may also occur, secondary to moderate/severe TBI. Examples include disinhibition, arousal disorders, and erectile dysfunction. If present, comprehensive assessment is appropriate in guiding therapeutic management.

Neuroendocrine Complications

Neuroendocrine abnormalities following moderate/severe TBI are common. These potential complications may require specialized medical evaluation and treatment if correlative symptoms exist and/or persist. Pharmaceutical treatment for other complications may also affect endocrine systems and require treatment.

Fluid and Electrolyte Complications

Abnormalities in individuals with moderate/severe TBI are usually iatrogenic or trauma induced. Specific problems may include, but are not limited to, a resulting water and salt retention with decreased urine output. There may also be problems with hyponatremia from inappropriate antidiuretic hormone, cerebral salt wasting, and increased production of aldosterone. Also, hypernatremia from dehydration or diabetes insipidus (DI) may occur. This may require careful evaluation with laboratory studies initially and serially on a follow-up basis.

Immobilization and Disuse Complications

In a comatose individual, skin is at risk for the development of pressure decubitus ulcers that may slowly progress and increase the length of hospital stays. Tissue pressure, shear, and deformation cause the ischemia. Vigilant rehabilitation nursing including accurate staging, specialized beds, wheelchair cushions, padding, positioning, and weight shift management, protects the individual from these complications.

Vascular Complications

Individuals with TBI are at risk for developing deep venous thrombosis (DVT) and pulmonary embolus (PE). Since diagnosis by clinical examination is difficult in this population, a high degree of suspicion is warranted. While in the hospital, daily nursing screening with lower extremity measurements is recommended. Abnormalities requiring confirmation may entail noninvasive studies such as Doppler ultrasonographic flow examination and impedance plethysmography. Also, hematologic conditions, such as, but not limited to, coagulopathies may require comprehensive specialized hematologic evaluation. It is generally accepted that prophylaxis with low molecular weight heparin, intermittent compression devices (ICDs), or sequential compression stockings may reduce the incidence of both complications. If the diagnostic use of non-invasive studies as mentioned are equivocal and/or non-confirmatory, then venography and/or angiography may be necessary. If thrombotic complications occur, standard treatment includes intravenous heparin or subcutaneous low molecular weight heparin followed by oral warfarin sodium. Other newer pharmaceutical agents may also be appropriate. If neuromedical risks of anticoagulation are present and/or complications related to anticoagulation or progressive thrombosis arise, then placement of an inferior vena cava filter may be necessary.

Non-operative Therapeutic Procedures—Rehabilitation

Interdisciplinary Rehabilitation Programs

This is the recommended treatment for individuals with MTBI who have not responded to less intensive modes of treatment and for moderate/severe TBI. These programs should assess the impact of the injury on the patient's medical, physical, psychological, social, and/or vocational functioning. The number of professions involved in the team in a TBI program may vary due to the complexity of the needs of the person served. The Division recommends consideration of referral to an interdisciplinary program based on the results of a comprehensive neuropsychological and/or psychiatric assessment, which should be conducted post-injury in MTBI individuals with delayed recovery and as soon as appropriate for more severe cases. The sequencing of treatment is based on the individual's ability to tolerate and benefit from the specific therapies. For example, a patient with severe balance problems will be unable to participate in physical rehabilitation.

Patients with addiction and/or substance abuse problems or high-dose opioid or other drugs of potential abuse may require inpatient and/or outpatient chemical dependency treatment programs before or in conjunction with other interdisciplinary rehabilitation. Guidelines from the American Society of Addiction Medicine are available and may be consulted relating to the intensity of services required for different classes of patients in order to achieve successful treatment.

Interdisciplinary programs may be considered for patients who are currently employed, those who cannot attend all day programs, those with language barriers, or those living in areas not offering formal programs. Before treatment has been initiated, the patient, patient's family and/or support system, physician, and insurer should agree on the treatment approach, methods, and goals. Generally the type of outpatient program needed will depend on the degree of impact the injury has had on the patient's medical, physical, psychological, social, and/or vocational functioning.

When referring a patient for integrated interdisciplinary rehabilitation, the Division recommends the program meets the criteria of the Commission on Accreditation of Rehabilitation Facilities (CARF).

There is good evidence that MTBI patients without PTA do not require routine multidisciplinary care. Inpatient rehabilitation programs are rarely needed for MTBI but may be necessary for patients with any of the following conditions: (a) high risk for medical instability; (b) moderate-to-severe impairment of functional status; (c) moderate impairment of cognitive and/or emotional status; (d) dependence on medications from which he or she needs to be withdrawn; and (e) the need for 24-hour supervision.

Programs should include the following dimensions:

- Communication
- Documentation
- Patient education
- Neuropsychological evaluation and treatment
- Psychosocial evaluation and treatment
- Treatment modalities (a complete list of active and passive therapies are included in the relevant sections of the original guideline)
- Therapeutic exercise programs
- Return to work
- Vocational assistance

Interdisciplinary brain injury programs are characterized by a variety of disciplines that participate in the assessment, planning, and/or implementation of the treatment program. These programs provide outcome focused, coordinated, goal-oriented interdisciplinary team services to measure and improve the functioning of persons and are for patients with greater levels of perceived disability, dysfunction, de-conditioning, and psychological involvement. Programs should have sufficient personnel to work with the individual in the following areas: behavioral, functional, medical, cognitive, pain management, psychological, social, and vocational. All programs for moderate/severe TBI should be able to address all of the associated neuromedical conditions listed in this guideline. Programs should share information about the scope of the services and the outcomes achieved with patients, authorized providers, and insurers.

The following programs are listed in alphabetical order. Refer to the original guideline document for specific information on each of these programs.

- Behavioral programs
- Comprehensive integrated inpatient interdisciplinary rehabilitation programs
- Home and community-based rehabilitation
- Nursing care facilities
- Occupational rehabilitation
- Opioid/chemical treatment programs
- Outpatient rehabilitation services
- Residential rehabilitation

- Supported living programs (SLP) or long-term care residential services

Activities of Daily Living (ADL) (also called daily living skills, life skills, or living skills)

ADLs are tasks necessary for an individual's day-to-day functioning, including both basic and instrumental level tasks. ADL functional limitations and disabilities in ADLs are common following TBI and are often due to changes in physical, cognitive, and emotional/behavioral impairments. Functional limitations and disability in these areas may range from mild to severe, as well as from short-term to life-long.

Therapeutic intervention for ADLs is generally accepted and widely used. The goal of treatment is to improve one's ability to perform such tasks, in order to increase functional levels of independence. There is good evidence in the stroke population that occupational therapy provides a modest reduction in disability and risk of death. By including ADLs in treatment, cognitive improvements may occur by applying cognitive rehabilitation principles to the task performance. Likewise, physical deficits may be improved by applying neuromuscular rehabilitation principles to the task performance.

The original guideline document provides additional information on basic and instrumental ADLs.

Mobility

Therapy

Individuals who have sustained a moderate/severe TBI may experience changes in their mobility control and may require medical, surgical, physical, and functional therapeutic management to improve their movement and function. Impairments may affect functional skills, including a propensity for falls, and may be seen in the following areas: bed mobility, wheelchair mobility, seating and positioning, transfers, and ambulation.

Therapeutic intervention supervised by a physical or occupational therapist is generally accepted and widely used to improve performance of mobility impairments. Treatment may include, but is not limited to, the areas of bed and mat mobility skills, sensory integration, endurance, balance, coordination, strengthening, stretching, gait training, neuromuscular re-education, and postural control. Training is also indicated for individuals and their family and/or support system in the areas of wheelchair mobility, seating and positioning, ROM, functional mobility (bed mobility, and transfers, ambulation), and therapeutic exercise. The use of modalities (functional electrical stimulation, transcutaneous electrical stimulation [TENS], ultrasound, phonophoresis, biofeedback) may be indicated to improve function. Passive modalities should not be utilized in isolation without a comprehensive therapeutic intervention program. Other indicated therapies may include pool therapy, casting/splinting programs, and facility-based exercise programs. Orthopedic and/or neuromuscular problems may develop along with mobility impairments. These may include, but are not limited to, heterotopic ossification, limb contractures, and abnormal tone, which may interfere with the advancement of independence with mobility skills.

Therapy to improve gait after moderate/severe TBI or stroke with foot drop or other gait difficulties, is variable and includes treadmill training with body weight support, unsupported treadmill walking, electromyographic biofeedback with therapy, use of gait assistive devices such as a stick or frames and other therapist-facilitated therapy. None of these therapies is clearly superior to another.

Refer to the original guideline document for additional information on music therapy and adaptive devices.

Environmental modifications may include, but are not limited to: ramping; modifications of the living environment to achieve reasonable levels of independence; and adaptive equipment for mobility and safety. Typically, these evaluations are done by a licensed contractor and occupational or physical therapist with experience in Americans with Disabilities Act (ADA) standards. Modifications must be medically necessary. Periodic upgrading of equipment and devices or consultation may be necessary throughout a person's lifetime following TBI.

Therapy related to equipment and devices may be re-initiated for time limited, goal-specific treatment as new goals are developed.

Ataxia

Ataxia is a common impairment in coordination resulting from the inability to control muscle timing and the sequencing of agonist and antagonist contraction. This will affect fine motor and gross motor skills of the extremities as well as general mobility, balance, gait, conditioning, endurance, and ADLs. Therapeutic management/intervention includes medication and neuromuscular re-education as well as functional activities, which facilitate normal or inhibit abnormal muscle activity. Specific exercises and activities increase motor learning and control and force production (strength) and endurance. Biofeedback and functional electrical stimulation may assist in treatment. Cognitive impairment may interfere with and prolong the course of therapy. Reasonable and necessary equipment may include splints and braces.

Neuromuscular Re-education

Neurologically based musculoskeletal impairment may include changes in reflexes, sensory integration, ROM, muscle tone, strength, endurance,

postural control, postural alignment, and soft tissue integrity. Functional abilities that are affected may include, but are not limited to, problems in gross and fine motor coordination, motor strength and control, sensory-motor bilateral integration, and praxis. Individuals with neuromuscular impairments may require physical, therapeutic, and medical and/or surgical management to improve their movement and mobility.

There is good evidence that constraint-induced motor therapy (CIMT) provides a favorable effect immediately post treatment for stroke victims with paresis of one arm and good cognition. There is some evidence that the motor function associated with CIMT is maintained at 24 months after treatment. Therefore, CIMT is a recommended therapy for similarly affected TBI patients.

Work Conditioning

These well-accepted programs are work-related, outcome-focused, individualized treatment programs. Objectives of the program include, but are not limited to, improvement of cardiopulmonary and neuromusculoskeletal functions (strength, endurance, movement, flexibility, stability, and motor control functions), patient education, and symptom relief. The goal is for patients to gain full or optimal function and return to work. The service may include the time limited use of modalities, both active and passive, in conjunction with therapeutic exercise, functional activities, general conditioning body mechanics, and re-training of lifting techniques. The patient should be assisted in learning to pace activities to avoid exacerbations.

These programs are usually initiated once re-conditioning has been completed but may be offered at any time throughout the recovery phase. It should be initiated when imminent return of a patient to modified or full duty is not an option, but the prognosis for returning the patient to work at completion of the program is at least fair to good.

Work Simulation

A generally accepted program where an individual completes specific work-related tasks for a particular job and return to work. Use of this program is appropriate when modified duty can only be partially accommodated in the work place, when modified duty in the work place is unavailable, or when the patient requires more structured supervision. The need for work place simulation should be based on the results of a functional capacity evaluation and/or jobsite analysis.

Muscle Tone and Joint Restriction Management, Including Spasticity

This is defined as velocity dependent hyperactivity of stretch reflexes secondary to the upper motor neuron syndrome. It is characterized by exaggerated deep tendon reflexes, increased muscle tone that results in a range of abnormal reflexes and motor patterns. The Modified Ashworth Scale is a clinical tool for measuring resistance to passive limb movement. If spasticity is interfering with the individual's general functioning (which may include ROM limitations, limitations in care and/or ADLs, and limitations in mobility), then treatment is often warranted. Individuals with moderate/severe TBI may demonstrate changes in muscle activation based on emotional factors, positional changes, and functional demands. Treatment approaches involve the disciplines of rehabilitation nursing, physical therapy, speech pathology, and occupational therapy. Therapeutic intervention should concentrate on active control, force production, and functional muscle use rather than just tone or spasticity reduction. Specific treatments may include, but are not limited to:

- Orthotics and casting
- Postural control
- Functional and therapeutic activities
- Therapeutic nerve and motor point blocks
- Botulinum toxin (Botox) injections
- Pharmaceutical agents
- Intrathecal baclofen drug delivery

Refer to the original guideline document for descriptions, indications, complications, and contraindications of the above treatments.

Non-operative Therapeutic Procedures—Vision, Speech, Swallowing, Balance & Hearing

Visual Treatment

Visual impairments may occur secondary to TBI. Treatment of visual impairments should be based on a comprehensive evaluation and diagnosis. Treatment should be functionally based and goal directed. Individuals should be evaluated at intervals depending on their impairment, and progress should be clearly documented. An ophthalmologist, neuro-ophthalmologist, neurologist, occupational therapist, or optometrist may treat visual impairment resulting from TBI. Treatment should be coordinated with the other interdisciplinary team members with the purpose of achieving the functional goals. Visual impairments may occur in one or more of the following categories:

- Visual acuity and visual field function
- Ocular motor control and ocular alignment
- Visual perception

Refer to the original guideline document for discussions of evaluation and treatment of the above visual impairments and visual inattention.

Note: Visual therapy is also performed for dizziness (refer to the "Vestibular Rehabilitation" section of the original guideline document).

Neuro-otologic Treatments

For patients with dizziness causing nausea or affecting balance, treatment of these conditions may be necessary before other rehabilitative therapy can be accomplished.

Refer to the original guideline document for a brief discussion of evaluation and treatment of the following otologic conditions:

Treatment of Fixed Lesions

- Post-traumatic tinnitus
- Hyperacusis/sonophobia
- Sensorineural hearing loss
- Vestibular loss

Treatment of Recurrent, Non-progressive Otologic Disorders

- Benign positional vertigo (BPV)
- Semicircular canal dehiscence
- Vestibular migraine
- Impaired compensation due to multisensory imbalance

Treatment of Progressive Otologic Disorders

- Progressive vestibulopathy with or without hearing loss
- Perilymphatic fistula

In-office Treatment Procedures

- Steroid perfusion
- Gentamicin perfusion
- The Meniett device

Tympanostomy

Tube placement may be needed for use of a Meniett device.

Vestibular Rehabilitation

Performed by qualified practitioners, e.g., audiologists, otologists, trained nurses, physical therapists (preferably neurology certified), or occupational therapists. Symptoms of vestibular system dysfunction following TBI may be due to damage of central or peripheral structures and may include vertigo, eye-head discoordination affecting the ability to stabilize gaze during head movements, and imbalance affecting stability in standing or walking. Dizziness is commonly associated with TBI. Dizziness and balance disorders may or may not co-exist in the same individual with TBI.

Refer to the original guideline for evaluation and treatment guidelines for:

- Balance disorders
- Postural control
- Dizziness
- Benign positional vertigo (BPV)

Swallowing Impairments (Dysphagia)

The incidence of swallowing disorders in the TBI population is high with presenting dysphagia usually characterized by a combination of oral and

pharyngeal stage deficits. Co-existing cognitive and behavioral deficits compromise swallowing safety. Physical damage to the oral, pharyngeal, laryngeal, and esophageal structures complicates neurogenic dysphagia. Prolonged ventilation, endotracheal intubation, and the presence of tracheostomy may also have a negative impact on swallow function.

The initial goal in oral-pharyngeal dysphagia intervention involves lessening the impact of the dysphagia through prevention of medical complications, such as aspiration pneumonia or malnutrition, and the establishment of alternative nutrition if necessary for the maintenance of adequate nutrition. A stimulation program without presentation of food may be provided early in the course of therapy in preparation for later feeding. In subsequent therapy, there is gradual introduction of oral nutrition using an array of treatment techniques designed to target the physiological impairments underlying the dysphagia while the individual continues to receive alternate nutrition. There is an eventual progression towards total oral nutrition without need for supplementation and independence with any safety precautions or therapy techniques.

Therapeutic strategies may be divided into two categories:

Compensatory Treatment

These include strategies such as postural adjustments of the head, neck and body to alter the dimensions of the pharynx; the flow of the bolus; altering consistency and viscosity of foods; and varying the volume and rate of presentation of the food or drink.

Therapy Techniques

Therapy techniques are designed to change the swallowing physiology. These include, but are not limited to, strategies such as, ROM and bolus control tasks to improve neuromuscular control, swallowing maneuvers which target specific aspects of the pharyngeal phase of the swallow, and swallowing maneuvers to facilitate laryngeal closure during the pharyngeal phase of the swallow. Neuromuscular electrical stimulation has also been used in conjunction with swallowing therapy; however, at the time of this guideline, the evaluation studies available do not meet evidence standards. Thus, it is not routinely recommended but may be used.

Communication

Speech-language therapy and occupational therapy are well-accepted and widely used. Music therapy may be appropriate for some patients.

There is insufficient evidence to recommend specific types of therapy.

Communication (speech-language) impairments are a common result of TBI and may be classified into the following groups: (1) motor speech disorders, which may take the form of dysarthria and/or apraxia of speech; (2) voice disorders; (3) language disorders; (4) communicative/cognitive disorders; and (5) fluency disorders. These may occur together in varying combinations in TBI.

Certified speech-language pathologists and occupational therapists are qualified to identify, evaluate, and determine the appropriateness of treatment for individuals with speech, language, and cognitive-communicative disorders.

For certain individuals, prosthetic or alternative augmentative communication (AAC) devices may be necessary to optimize communicative success. These include, but are not limited to: (1) palatial lift prostheses for velopharyngeal dysfunction resulting in severe impairment in speech intelligibility; and (2) augmentative or alternative communication devices which may be indicated when speech is inadequate for functional communication. AAC may involve the use of simple gesture systems, alphabet boards, pictures, word books, or sophisticated use of computer technology (speech generation devices). AAC strategies may enhance communicative participation by replacing, supplementing or scaffolding residual natural speech and providing a means of repairing disrupted communication.

Melodic intonation therapy is a structured therapy that trains verbal reproduction with melodically intoned phrases while tapping the patient's hand.

The process of deciding on these techniques or devices and the training in their use is integrated into the individual's ongoing evaluation and therapy plan.

Non-operative Therapeutic Procedures—Return to Work, Driving & Other

Driving

Self report of feeling confident with driving ability may not be reliable. An individual's ability to drive is typically evaluated and treated under physician orders by a certified driver rehabilitation specialist. Physicians, neuropsychologists, or rehabilitation therapists can perform an initial screening to determine driving ability by assessing visual acuity, visual fields, memory, visual perception, visual processing, visual spatial skills, selective and divided attention, executive skills, motor and sensory function coordination, pain, and fatigue.

A thorough history should be taken which includes: (1) a review of all medication that might affect cognition or coordination; (2) screening for sleep

apnea (body mass index [BMI] >35, neck size >15.5 inches, for female or 17 inches for males, daytime sleepiness, Eppworth Sleepiness Scale score of 10 or greater, two or more hypertension medications); (3) history of accidents and/or tickets; and (4) consultation with family and/or support system members or others regarding driving ability. Reluctance of others to ride with the patient may be an indication of problems. Patients may also fill out surveys that have some predictive abilities. Unfortunately, at the time of this guideline, there is no evidence for the use of one system of assessment over another to predict driving skills.

In addition, the treatment and evaluation process may require the services of a:

- Commercial driver trainer for driving practice
- Ophthalmologist or optometrist for visual evaluation
- Commercial vendor and rehab engineer for adaptive equipment
- Neuropsychologist for cognitive evaluation
- Speech-language pathologist for communication evaluation and compensatory strategies
- Occupational or physical therapist with expertise in acquired brain injury

Public and personal safety and compliance with state department of motor vehicles procedures ultimately determine individual driving privileges. Evaluation and treatment typically occur during the post-acute phase of rehabilitation. Usually, successful driving results are obtained within the first two years post-injury, but this is not always the case.

If the individual fails the evaluation, he or she may be required to participate in additional driving practice and repeat the behind-the-wheel test, or to wait three months or longer to repeat the evaluation. The evaluation may be repeated at three- to 12-month intervals as determined by the evaluator and physician. Several repeat assessments may be necessary to determine safe driving readiness.

Recommendations and physician prescriptions for necessary adaptive equipment and vehicle modification for safe driving or for dependent passenger transport in vehicles may be necessary.

Return to Work

In addition to the treatment strategies described below, practitioners should be familiar with how various state and federal statutes and regulations may impact return-to-work planning. These may include, but are not limited to, Family and Medical Leave Act (FMLA), Americans with Disabilities Act (ADA), Occupational Health and Safety Administration (OSHA), Federal Motor Carrier Safety Administration (FMCSA), and the Department of Transportation (DOT). In places where the employer is unable to accommodate, other options include sheltered work shops.

Return to Work – MTBI

During the first five days post-injury, symptoms can be severe and significantly disrupt normal daily function. Initial considerations should include lightening task load and allowing extra time to complete normal tasks. Thus, shortening the work day or adding breaks, along with decreased responsibility for the first several weeks are generally suggested. Driving, heavy lifting, working with dangerous machinery, use of ladders, and heights may be restricted because of possible safety risk. For individuals with MTBI who have persistent deficits, or who have difficulty once back at work, a return-to-work program requires a carefully designed and managed plan involving the person with TBI, his/her employer, and the treatment team. Physicians should consider evaluation and treatment for co-morbid conditions such as chronic pain, stress level, pre-existing personality disorders, depression, anxiety, and/or substance abuse. Communication among all involved parties and the avoidance of fragmentation among treatment professionals is critical to successful outcome. Case management may be indicated to facilitate communication. Following return to work, maintenance support services are appropriate to best insure the durability of the outcome.

Refer to the original guideline for additional discussion of return to work in individuals with MTBI.

Return to Work – Moderate/Severe TBI

Following moderate/severe TBI, some individuals are unable to return to work. Successful return to work among individuals with moderate/severe injury may require an interdisciplinary approach including neuropsychological assessment, speech-language assessment, functional capacity evaluation, job site analysis, early contact with employer, assessment of vocational feasibility, transferable skills analysis, supervisor education, job coaching, skillful increased titration of job duties and demands, mental health, family counseling, and follow-up services.

The following should be considered when attempting to return an injured worker with moderate/severe TBI to work:

- Job history interview
- Coordination of care
- Communication

- Establishment of return-to-work status
- Establishment of activity level restrictions
- Rehabilitation and return to work
- Vocational assistance

Vocational Rehabilitation

Vocational rehabilitation is a generally accepted intervention, but the Colorado Workers' Compensation statute limits its use. Initiation of vocational rehabilitation requires adequate evaluation of individuals with TBI for quantification of highest functional level, motivation and achievement of maximum medical improvement (MMI). Vocational rehabilitation should involve a comprehensive job analysis and a carefully planned return to work strategy. In some instances, retraining may need to occur to access new job markets (refer to the "Return to Work" section above and in the original guideline document).

Complementary and Alternative Medicine (CAM) (as defined by the National Center for Complementary and Alternative Medicine [NCCAM])

CAM is a group of diverse medical and health care systems, practices, and products that are not presently considered to be part of conventional medicine. CAM includes a wide range of interventions, some of which have not been supported by empirical data. These alternative treatments include, but are not limited to: art therapy, craniosacral trauma release, electroencephalography (EEG) neuro feedback, dance therapy, hippotherapy, hypnosis, and horticulture therapy. CAM uses methods of treatment based on a broad range of knowledge with roots in both eastern and western medicine. Many providers may integrate more than one procedure. Some of these interventions, including the exercise-based procedures, are currently integrated into ongoing rehabilitation programs. In general, most approaches place major focus on the important relationship between physical and emotional well-being.

Acupuncture, biofeedback, and cervical spinal manipulations are widely accepted and may be used for headaches or other painful conditions.

Other Treatments

Hyperbaric Oxygen

Studies in this area demonstrated a possible decrease in morbidity for severely injured patients but no clear overall improvement in outcome. It is also associated with possible long-term pulmonary damage. It is considered investigational at this time and not recommended.

Deep Thalamic Stimulation

This technique has been used in some cases of stroke with motor and cognition problems. There are no studies reported on patients with TBI. It is considered investigational at this time and generally not recommended. It may be used for patients with severe spasticity or motor problems who have failed other treatments.

Transcranial Magnetic Stimulation

This is a noninvasive treatment and exploratory diagnostic tool that is FDA approved for use in major depression resistant to other therapy. Some patients have experienced seizures as a side effect. There is no evidence for its use in TBI, and it is not recommended for TBI or for comatose or vegetative patients. It is considered experimental for these conditions.

Operative Therapeutic Procedures

It is not the intent of medical treatment guidelines to provide an exhaustive list of surgical procedures associated with TBI. Instead, an overview of the general categories is presented to illustrate the wide range of procedures that are widely accepted for treatment of individuals with TBI. Combinations and variations on procedures should be tailored to specific cases; hence, a variety of procedures based on the clinical judgment of the treating physician is to be expected. Common procedures include, but are not limited to:

Extracranial Soft Tissue

- Debridement and closure
- Plastic or reconstructive

Maxillofacial

- Repair and stabilization of fracture
- Facial nerve decompression
- Repair and/or reconstruction

Skull

Debridement, elevation, and/or repair of fracture or defect including cranioplasty

Brain

- Debride penetrating injury, gunshot wound, or foreign body
- Decompression and evacuation
  - Hematoma: epidural, subdural, intraparenchymal
  - Contusion
  - Infections: abscess or empyema
- Decompressive craniectomy

Cerebral Spinal Fluid (CSF)

- CSF leak or fistula: Lumbar spinal drain or serial lumbar puncture may be used as option to promote spontaneous resolution of CSF leak, or as adjunct to surgical repair.
- Ventricular shunting
- Ventriculostomy

Ophthalmologic

- Direct trauma to globe and/or orbital contents
- Repair orbital fractures, decompression of orbital contents
- Optic nerve decompression (immediate surgery may be indicated if the trauma results in entrapment or compression of the nerve, or if a hematoma is present in the optic nerve sheath)
- Strabismus: surgery may be required to eliminate or decrease diplopia
- Vitrectomy may be indicated in cases of vitreous hemorrhage
- Surgery may be indicated in cases of eye-lid abnormalities, lacrimal disorders, and other traumas to the external ocular structures

Otologic

- Direct trauma or barotrauma:
  - Ossicular discontinuity: The mechanism of head trauma causing TBI may result in dislocation of the hearing bones, creating a conductive hearing loss. This would require an exploratory tympanostomy with ossicular replacement to correct.
  - Tympanic membrane perforation: Tympanoplasty is indicated for correction.
- Tympanostomy
- Middle ear exploration:
  - Perilymphatic fistula repair
  - Endolymphatic sac surgery
  - Labyrinthectomy
- Vestibular nerve section

Decompression of Facial Nerve

If there is immediate onset of total facial paralysis, or if the electroneuronography (EnoG) shows greater than 90% degeneration of the facial nerve, then exploration of the path of the facial nerve is indicated. This usually involves a middle fossa craniotomy and mastoidectomy in order to completely decompress the facial nerve.

Other Cranial Nerve Repair or Decompression

May be required for functionally disabling conditions such as diplopia

Vascular Injury

- Endovascular procedures (i.e., stent, embolism)
- Direct repair
- Occlusion, trapping, aneurysm repair

Peripheral Nerve Injury

May include decompression and repair and/or fracture management.

Orthopedic

- Fracture management
- Adjunctive tenotomies and myotomies
    - Common upper extremity procedures may require pre-surgical evaluation inclusive of occupational therapy, ROM, function, diagnostic nerve blocks, and dynamic EMG. Definitive procedures include, but are not limited to:
        - Shoulder muscle release
        - Functional elbow release: brachial radialis myotomy, biceps and brachialis lengthening
        - Fractional lengthening of wrist and/or finger flexors
        - Flexor digitorum superficialis (FDS) to flexor digitorum profundus (FDP) transfer
        - Intrinsic muscle contracture release
        - Surgical release of thenar muscles for thumb in palm deformity
        - Individualized and customized procedures for spastic upper extremity deformities with adjunctive selective musculotendinous transfers, neurotomy and neurectomies
    - Common lower extremity procedures include, but are not limited to:
        - Fractional muscle lengthening of knee flexors/hamstrings
        - Hip flexor releases/myotomies
        - Percutaneous vs. open release of the hip adductors
        - Percutaneous tendon Achilles lengthening
        - Ankle/foot motor balancing surgery adjunctive to tendon-Achilles lengthening (TAL procedure) includes:
            - Toe flexor release
            - Split anterior tibial tendon transfer (SPLATT procedure)
            - Interphalangeal joint fusions
            - Ankle fusions
        - Individualized and customized procedures for spastic lower extremity deformities with adjunctive selective musculotendinous transfers, neurotomy, and neurectomies
    - Resection heterotopic ossification

Spasticity

- Spinal cord procedures, including percutaneous and open selective dorsal rhizotomy (SDR)
- Intrathecal baclofen (ITB) pump: The pump is surgically implanted in the abdomen (refer to the "Intrathecal Baclofen Drug" section above and in the original guideline document)
- Other "tone management" procedures

Clinical Algorithm(s)

A headache treatment algorithm is provided in the original guideline document.

Scope

Disease/Condition(s)

Traumatic brain injury (TBI) and TBI complications

Guideline Category

Management

Rehabilitation

Treatment

Clinical Specialty

Emergency Medicine

Family Practice

Internal Medicine

Neurological Surgery

Neurology

Nursing

Ophthalmology

Physical Medicine and Rehabilitation

Psychiatry

Psychology

Sleep Medicine

Speech-Language Pathology

Surgery

Intended Users

Advanced Practice Nurses

Chiropractors

Emergency Medical Technicians/Paramedics

Health Care Providers

Health Plans

Hospitals

Nurses

Occupational Therapists

Physical Therapists

Physicians

Psychologists/Non-physician Behavioral Health Clinicians

Social Workers

Speech-Language Pathologists

Utilization Management

Guideline Objective(s)

To provide advisory and educational guidelines for the treatment of traumatic brain injury that are enforceable under the Colorado Workers' Compensation Rules of Procedure

Target Population

Patients with traumatic brain injury who qualify for treatment under Colorado's Workers' Compensation Act as an injured worker

Interventions and Practices Considered

1. Non-operative acute therapeutic procedures*
    - Resuscitation
    - Intracranial pressure (ICP) and cerebral perfusion pressure (CPP) monitoring
    - Hyperventilation
    - Hyperosmolar agents
    - Glucocorticoids (steroids)
    - Anticonvulsants
    - Progesterone
    - Hypothermia
    - Surgery
    - Hyperbaric oxygen
2. Non-operative therapeutic procedures*
    - Initial treatment considerations
        - Patient/family/support system education
        - Behavior
        - Cognition
        - Psychological/education interventions
        - Affective disorders medications
        - Behavior/aggression medications
        - Cognitive enhancers
        - Hypnotics and sedatives
        - Non-steroidal anti-inflammatory drugs
        - Skeletal muscle relaxants
        - Opioids
        - Management of headache
        - Botulinum injections
        - Therapeutic exercise
        - Management of sleep disturbances
    - Management of neuromedical conditions in moderate/severe brain injury, including post-traumatic seizures/post-traumatic epilepsy (PTE) and neurological, cardiopulmonary, sleep, musculoskeletal, gastrointestinal, genitourinary, neuroendocrine, fluid and electrolyte, immobilization and disuse, and vascular complications
    - Rehabilitation
        - Interdisciplinary rehabilitation programs
        - Therapeutic interventions for activities of daily living (ADLs) (basic and instrumental)
        - Mobility therapy and adaptive devices
        - Ataxia management (medication, neuromuscular re-education, and functional activities)
        - Work conditioning
        - Work simulation
        - Muscle tone and joint restriction management (orthotics and casting, postural control, functional and therapeutic activities, therapeutic nerve and motor point blocks, Botulinum toxin [Botox] injections, pharmaceutical agents, intrathecal baclofen drug delivery)
    - Vision, speech, swallowing, balance and hearing
        - Visual treatment
        - Neuro-otologic treatments

        - Management of swallowing impairments (dysphagia)
        - Management of communication impairment (speech-language therapy, occupational therapy, music therapy)
    - Return to work, driving and other
        - Assessment of driving ability
        - Return to work considerations
        - Vocational rehabilitation
        - Complementary and alternative medicine (CAM)
        - Hyperbaric oxygen
        - Deep thalamic stimulation
        - Transcranial magnetic stimulation
3. Operative therapeutic procedures (see the "Major Recommendations" field)

*Note: See the "Major Recommendations" field and the original guideline document. Not all of the listed interventions and practices are recommended routinely or generally.

Major Outcomes Considered

- Functional improvement (time to return to work, ability to return to original job, etc.)
- Duration of therapeutic effect
- Treatment parameter duration
- Side effects or complications

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

General Literature Search Strategy

Studies were identified through the electronic database of PubMed (with specified search topics), and related links from articles identified by searches. For some articles, Web of Science, a literature citation database, was used when it was desirable to find literature that cited a particular article. Relevant evidence statements from Cochrane and British Medical Journal (BMJ) Clinical Evidence were reviewed. Selected guidelines/systematic reviews were also reviewed. The reference lists from other literature and Tables of Contents from related journals were scanned for relevant articles. Suggestions from various volunteer advisory bodies to the Division of Workers' Compensation were solicited.

Literature reviewed was in English. Literature searches were limited according to study type and human adults. Only randomized controlled trials (RCTs) or meta-analyses were used for evidence statements regarding treatment. Beginning with the Traumatic Brain Injury Medical Treatment Guidelines Revision of 2012, if meta-analyses were of high enough quality, then previous RCTs that were incorporated into the selected meta-analyses may not have been individually critiqued. Selected RCTs published after Cochrane meta-analyses were evaluated as to whether they would have likely met the Cochrane inclusion criteria. If so, the Cochrane software (RevMan) was used to update the pooled effect measure and compare it with the original Cochrane report. Diagnostic accuracy studies were critiqued for diagnostic testing evidence and cohort, cross-sectional and case-control studies were critiqued for causation evidence statements. Literature which did not meet requirements for evidence statements could be referenced if it furnished useful background information or described interventions which are considered generally accepted by a consensus of health care providers. This information sometimes contributed to consensus decisions by the multi-disciplinary task force drafting the guidelines. Literature that was determined to be unrelated to the clinical issue, or which had such poor quality on initial review that it could not qualify for evidence nor provide meaningful input was not critiqued. All articles sent by the public were formally reviewed.

Specific Search Strategy

All searches were done on PubMed. The literature search included articles published from 2004 to 2012, with some searches incorporating a broader range of dates to address input from stakeholders. The search was conducted between August 2011 and June 2012.

Search terms: Diffuse axonal injury, Penetrating head injuries, Cerebrovascular trauma, Traumatic cerebral hemorrhage, Closed head injuries, Mild traumatic brain injury, Traumatic brain injury, TBI and modafinil, TBI and memantine, TBI and donepezil, TBI and amantadine, TBI and bromocriptine, TBI and physostigmine, TBI and methylphenidate, TBI and dexanabinol, TBI and rivastigmine, TBI and aminosteroids, TBI and citicoline, TBI and endocannabinoids, TBI and tacrine, TBI and cabergoline, TBI and magnesium, TBI and cyclosporine, TBI and Substance P antagonists, TBI and DDAVP, TBI and tranexamic acid, TBI and piracetam, TBI and craniectomy, TBI and QEEG, TBI and CT, TBI and MRI, TBI and brain acoustic monitor, TBI and visual perception, TBI and executive function, TBI and rehabilitation, TBI and cognitive rehabilitation, TBI and transcranial magnetic stimulation, TBI and induced hypothermia, TBI and neuroplasticity, Posttraumatic headache, TBI and headache, TBI and depression, mTBI and MRI, mTBI and CT, mTBI and diffusion tensor imaging, mTBI and SPECT, Neuromuscular electrical stimulation and swallowing, Meniett Device, Tinnitus, Aphasia, Spinal manipulation AND headache, Migraine AND TBI, Migraine AND botulinum toxin, Tension headache AND TBI, Tension headache AND botulinum toxin, Seizure disorders AND TBI, Whole body vibration AND TBI, Whole body vibration AND stroke, Neuromuscular electrical stim AND TBI, Functional electrical stim AND TBI, Robotics AND TBI, Biofeedback AND spasticity, Biofeedback AND traumatic brain injury, Laser therapy AND TBI, Body weight support treadmill training AND TBI, Body weight support treadmill training, Constraint-induced movement therapy AND TBI, Constraint-induced movement therapy AND stroke

Medical Literature Review

Articles are selected for review based on relevance and informativeness after viewing their titles and abstracts.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Subjective Review

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Grading of Systematic Reviews and Meta-Analyses*

Criterion	Green	Yellow	Red	Comments
The study is in fact identified as a systematic review or meta-analysis	"Systematic review," "meta-analysis," or both, are in the title of the article, and the abstract supports the design in the title	The title is ambiguous, but the abstract shows that the authors did a systematic review	The article is a narrative review or an overview, or is done by a single author	"Systematic review" and "meta-analysis" are generally recognized terms for a specific type of original research; narrative reviews are subject to biases which systematic reviews and meta-analyses methodically control for
Objectives of the systematic review or meta-analysis	Clearly stated in terms of PICOS: Patient population (disease, age, setting), Intervention (dose, frequency, etc.), Comparator (control group interventions), Outcome (morbidity, mortality, symptoms, function), and Study design (randomized trials only, broader design criteria)	PICOS elements all reported, but some ambiguity in some elements (e.g., Comparator described as "standard care" or "usual care" without further description)	One or more PICOS element missing or uninterpretable	The question being addressed should be clear from the abstract; it may be narrow or broad, but the scope and potential applicability should be well defined

Criterion	Green	Yellow	Red	Comments
Characteristics of eligible studies	In addition to PICOS, study characteristics defined in terms of restrictions for inclusion (e.g., minimum length of follow-up, whether co-interventions are included), and scope of reports (language, years of publication, unpublished material)	Ambiguity exists for some of the characteristics of eligible studies	Eligibility of studies is unclear, and scope of reports is not specified	
Information sources	Multiple information sources are clearly specified: databases (PubMed, Ovid, EMBASE, Cochrane, Web of Science), hand searches of tables of contents of relevant journals, meeting abstracts, reference lists, contacts with authors, manufacturers, trial registries)	Search limited to published material from two or more sources, without additional searching of registries or contact with authors	Search limited to a single information source (e.g., PubMed only)	While PubMed is a large and nearly comprehensive database, its yield can be influenced by how articles are indexed by the National Library of Medicine; additional sources of information can materially affect the conclusions of a systematic review or meta-analysis
Search strategy	Full electronic search strategy for at least one major database, with dates (e.g., PubMed 1970-October 2009), limits, combinations of search terms, such that it can be replicated by the reader	Databases and search terms are given, but there is some ambiguity in the strategy (e.g., PubMed "through 2007"), and replication by the reader would be difficult	Databases and search terms are too broad and vague to permit replication by the reader	Often given in an appendix to the article or in an online supplement, the strategy should be readily accessible
Study selection	Specification of which criteria determine eligibility for inclusion (e.g., randomization to specified interventions, which outcomes were required to be reported) and for quality (e.g., allocation concealment, intention-to-treat analysis, blinding) with at least two reviewers identified by initials; inter-rater agreement and methods of resolving disagreement are specified; a flow diagram enumerates articles retrieved from search, articles excluded after screening, and articles included for meta-analysis	Two or more reviewers screen articles for inclusion, but there is some ambiguity in the criteria for inclusion or for inter-rater agreement and methods of resolving disagreement; flow diagram is lacking	Only one reviewer selects studies; criteria are vague	Quality assessment should focus on risk of bias; scoring of articles for quality is not necessary and may be misleading. There is no standard process for selecting studies, but the process used by the reviewers should be clear enough to allow the reader to determine which studies might meet the test of inclusion
Outcomes for analysis	Meta-analysis is restricted to pre-specified primary and secondary outcomes, and exploratory (hypothesis-generating) analyses in the source literature are excluded from meta-analysis	Meta-analysis combines pre-specified primary and secondary outcomes in the source literature with exploratory analyses in the same literature, but assigns exploratory analyses a lower weight	Meta-analysis treats exploratory analyses in source literature on an equal basis with the pre-specified primary and secondary analyses	Exploratory analyses are too likely to be reported when they arise from the play of chance, and should not be included in any meta-analysis of the same outcomes; their inclusion is likely to bias the meta-analysis
Summary measures for meta-analysis with or without pooled Number Needed to Treat (NNT)	Principal summary measures (relative risk, risk difference, odds ratio, difference in means, hazard ratio) are specified and appropriate to the outcome measure; if numbers needed to treat (NNT) are reported, there is a fixed event rate in the control groups for the studies being combined	Risk ratios or odds ratios are reported, and NNT is not reported if there is a difference in the control group event rates across the different studies	Risk ratios or odds ratios are reported, but NNT is reported even when there is a difference in control group event rates across the different studies	Relative risks and odds ratios are generally more stable for summary measures than risk differences; pooled NNT is misleading if the control group event rate (the baseline risk) is different across studies, even if the risk ratio is the same

Criterion	Green	Yellow	Red	Comments
			(the underlying baseline risks are not equal)	
Meta-analysis presentation	Results of meta-analysis are presented as an estimated summary effect (with confidence interval) across all included studies, displaying a forest plot with weights and confidence intervals for the included studies; a measure of heterogeneity is presented (e.g., I^2); the choice of fixed effect or random effects model is explained, and, if there is significant heterogeneity, there is an attempt to examine possible sources of heterogeneity	Estimated summary effect with confidence interval, with an estimate of heterogeneity, and an explanation of the choice of fixed or random effects model; however, an examination of sources of heterogeneity is lacking	Summary effect measure with confidence interval, but heterogeneity measures and examinations are lacking	No hard and fast rule dictates the choice of model, but because a fixed effect model assumes a single common effect size across studies, there should be a discussion of why it is appropriate for the included studies

*See the Colorado Division of Workers' Compensation Web site for rating schemes for randomized controlled trials and accuracy of tests to rule out disease.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

Medical Literature Review

Published journal articles are selected to be critiqued by the Research Methodologist prior to distribution. Unpublished articles or office handouts submitted by Task Force members or the public are reviewed and critiqued by the Medical Director and Research Methodologist, who then communicate directly with the submitting individual regarding quality and relevance. The submitting individual retains the prerogative of distributing the material to the Task Force. Other unspecified material and public commentary received or solicited by the Division is reviewed and critiqued, as appropriate, and distributed at the discretion of the Medical Director and Medical Policy staff. Many articles are included in the bibliography without critiques or assessment for evidence. These articles are considered to provide pertinent information whether or not they lend themselves to formal evaluation for levels of evidence.

Over 500 articles and literature were examined for consideration during the course of this update. A limited number of articles qualified for evidence statements. The designated strength of the evidence (e.g., some, good, strong) may not coincide with acceptability of treatment. Each level of evidence was assigned in accordance with a related grading scheme. Where applicable, literature was given a designation of one of the following: high quality, adequate, inadequate, or not applicable. It should be noted that some articles might have more than one assigned level, such as, "adequate" on one concept and "high-quality" on another concept. The details regarding level of evidence assignment are discussed in the related critiques (see the "Availability of Companion Documents" field). Articles that were used to assign some, good, or strong evidence are identified in the bibliography with an asterisk (see the "Availability of Companion Documents" field).

When the evidence is conflicting or inconclusive, acceptability of treatment is determined by a combination of available medical literature and group consensus. Some of the elements that are considered in making consensus determinations are: level of functional benefit, acceptable risk/morbidity/mortality, and acceptable cost.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Guidelines Updating Process

The State of Colorado Division of Workers' Compensation Medical Treatment Guidelines updating process is completed in several stages. Initially, current medical literature related to the guideline is systematically reviewed, critiqued, and graded by the Division and the multi-disciplinary Task Force. Next, appropriate medical evidence and consensus are incorporated concurrently into the Guideline, section by section. During this stage, Task Force members will be appointed for projects, working in sub-groups or individually, according to the task.

Guideline updating processes and resources dedicated to supporting the Task Force includes:

- Medical literature review and grading, with the assistance of a professional Research Methodologist
- Evidence and consensus parameters to assist in the revision and evaluation of treatment recommendations
- A multi-disciplinary Advisory Panel and other advisory bodies to provide clinical feedback to the Task Force and the Division
- Administrative support and coordination, allowing participants to focus on clinical issues
- Opportunities for members to provide feedback on ways to improve the update process

Selection of Task Force Members

Health care disciplines required to participate in the task force process are identified. Individuals selected should be Level I or II Accredited Providers (if applicable), Board Certified in their area of specialty, in good standing within their medical specialty organization, and specialize in treatment of injured workers. Task force membership also includes non-physician members of the workers' compensation system, such as: therapists, psychologists, attorneys, and risk managers. Prior task force participation is not necessary.

Grading Recommendations

Graded consensus recommendations were developed based on the considered judgment of the multi-disciplinary Task Force, which considered the volume and consistency of the evidence and the generalizability and clinical impact of the recommendations.

Rating Scheme for the Strength of the Recommendations

Grades of Recommendation

Some means the recommendation considered at least one adequate scientific study, which reported that a treatment was effective.

Good means the recommendation considered the availability of multiple adequate scientific studies or at least one relevant high-quality scientific study, which reported that a treatment was effective.

Strong means the recommendation considered the availability of multiple relevant and high quality scientific studies, which arrived at similar conclusions about the effectiveness of a treatment.

Cost Analysis

The guideline developers reviewed published cost analyses.

Method of Guideline Validation

External Peer Review

Description of Method of Guideline Validation

Advisory Panel

The Guidelines update process includes an additional review, conducted by an Advisory Panel and other advisory bodies that may consist of past Task Force members and clinical experts representing medical specialty organizations and associations. Professionals representing adjunct aspects of patient care, such as Risk Managers, Case Managers, and Insurers, are also included in this stage. The purpose of the external review is to provide additional sources of expertise in order to finalize draft guideline material developed by the Task Force.

Solicitation of Public Commentary

An active, open process to solicit public commentary on a year-round basis is in place in order to maximize community-based physician input and support. Contact with Accredited Providers is done through direct mailings and at Accreditation seminars.

Post Task Force Questionnaire

A survey will be sent to all Task Force members once the updated draft guidelines are completed. The survey will rate Task Force participants' satisfaction with the processes used, and evaluate Division personnel and performance. Information may be used to improve future Task Force processes.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

Only randomized controlled trials or meta-analyses were used for evidence statements regarding treatment.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Optimal medical and functional outcomes for injured workers with traumatic brain injury

Potential Harms

- Injuries, side effects, or infections from therapeutic injections
- Side effects and drug interactions from medications
- Complications from operative procedures
- Injury from device or component failure

See specific sections of the original guideline document for detailed descriptions of potential harms.

Contraindications

Contraindications

- Absolute contraindications to diagnostic injections include, but are not limited to: (a) bacterial infection-systemic or localized to the region of injection, (b) bleeding diathesis, (c) hematological conditions and (d) possible pregnancy.
- Relative contraindications of diagnostic injections may include: (a) allergy to contrast, (b) aspirin/antiplatelet therapy (drug may be held three days or more prior to injection), and (c) shellfish allergy if contrast is to be used.
- Surgical pump implantation: Infection or body size insufficient to support the size and weight of the implanted device. Individuals with other implanted programmable devices should not be given these pumps, since interference between devices may cause unintended changes in infusion rates
- Lumbar puncture is contraindicated in acute trauma to the spinal column, certain infections, increased intracranial pressure due to space occupying lesions, and in some coagulation disorders or defects. Additionally, it should be avoided if there are cutaneous infections in the region of the puncture site.

See specific sections of the original guideline document for additional contraindications to medications and other therapeutic interventions.

Qualifying Statements

Qualifying Statements

- This document has been prepared by the Colorado Department of Labor and Employment, Division of Workers' Compensation (Division) and should be interpreted within the context of guidelines for physicians/providers treating individuals who qualify as injured workers with traumatic brain injury (TBI) under the Colorado Workers' Compensation Act.
- Although the primary purposes of this document for practitioners are advisory and educational, this guideline is enforceable under the Workers' Compensation Rules of Procedure, 7 CCR 1101-3. The Division recognizes that acceptable medical practice may include deviations from this guideline, as individual cases dictate. Therefore, this guideline is not relevant as evidence of a provider's legal standard of professional care.
- The Division provides procedures to implement medical treatment guidelines and to foster communication to resolve disputes among the provider, payer and patient through the Worker's Compensation Rules of Procedure. In lieu of more costly litigation, parties may wish to seek administrative dispute resolution services through the Division or the office of administrative courts.
- To properly utilize this document, the reader should view the document in its entirety for proper context and should not skip or overlook any sections.

Implementation of the Guideline

Description of Implementation Strategy

The principles summarized in this section are key to the intended implementation of this guideline and are critical to the reader's application of the guidelines in this document.

1. Application of Guidelines. The Division provides procedures to implement medical treatment guidelines and to foster communication to resolve disputes among the provider, payer, and patient through the Workers' Compensation Rules of Procedure. In lieu of more costly litigation, parties may wish to seek administrative dispute resolution services through the Division or the Office of Administrative Courts.
2. Education. Education of the individual and family and/or support system, as well as the employer, insurer, policy makers, and the community should be the primary emphasis in the treatment of traumatic brain injury (TBI) and disability. Practitioners often think of education last, after medications, manual therapy, and surgery. Practitioners should develop and implement an effective strategy and skills to educate individuals with TBI, employers, insurance systems, policy makers, and the community as a whole. An education-based paradigm should always start with inexpensive communication providing reassuring information to the individual with TBI. More in-depth education currently exists within a treatment regimen employing functional restoration and rehabilitation. No treatment plan is complete without addressing issues of individual and family and/or support system education as a means of facilitating self-management of symptoms and prevention.
3. Treatment Parameter Duration. Time frames for specific interventions commence once treatments have been initiated, not on the date of injury. Obviously, duration will be impacted by the individual's compliance, as well as availability of services. Clinical judgment may substantiate the need to accelerate or decelerate the time frames discussed in this document.
4. Active Interventions. Emphasizing personal responsibility, such as therapeutic exercise and/or functional treatment, are used predominantly over passive modalities, especially as treatment progresses. Generally, passive and palliative interventions are viewed as a means to facilitate progress in an active rehabilitation program with concomitant attainment of objective functional gains.
5. Active Therapeutic Exercise Program. Goals should incorporate strength, endurance, flexibility, coordination, and education. This includes functional application in vocational or community settings.
6. Positive Patient Response. Results are defined primarily as functional gains which may be objectively measured. Objective functional gains include, but are not limited to, positional tolerances, range of motion (ROM), strength and endurance, activities of daily living (ADLs), cognition, psychological behavior, and efficiency/velocity measures that may be quantified. Subjective reports of pain and function should be considered and given relative weight when the pain has anatomic and physiologic correlation. Anatomic correlation should be based upon objective findings.
7. Re-evaluation of Treatment Every Three to Four Weeks. If a given treatment or modality is not producing positive results within three to four weeks, the treatment should be either modified or discontinued. Reconsideration of diagnosis should also occur in the event of poor response to a seemingly rational intervention.
8. Surgical Interventions. Should be considered within the context of expected functional outcome and not solely for the purpose of pain relief. The concept of "cure" with respect to surgical treatment by itself is generally a misnomer. Clinical findings, clinical course, and diagnostic

tests must be consistent to justify operative interventions. A comprehensive assimilation of these factors must lead to a specific diagnosis with positive identification of pathologic condition(s).

9. Return to Work. Following TBI involves a skillful match between the individual's abilities (physical, cognitive, emotional, and behavioral) and the work requirements.
   The practitioner must write detailed restrictions when returning an individual with TBI to limited duty. An individual with TBI should never be released to "sedentary or light duty" without specific physical or cognitive limitations. The practitioner must understand all of the physical, visual, cognitive, emotional and behavioral demands of the individual's job position before returning him/her to full duty and should request clarification of job duties. Clarification should be obtained from the employer or others if necessary, including but not limited to: an occupational health nurse, occupational therapist, physical therapist, speech therapist, vocational rehabilitation specialist, case manager, industrial hygienist, or other appropriately trained professional.

10. Delayed Recovery. All individuals with moderate/severe TBI will require an integrated system of care. For individuals with mild TBI (MTBI), strongly consider requesting a neuropsychological evaluation, if not previously provided. Interdisciplinary rehabilitation treatment and vocational goal setting may need to be initiated for those who are failing to make expected progress 6 to 12 weeks after an injury. In individuals with MTBI, neurological recovery is generally achieved within a range of weeks/months up to one year post-injury, but functional improvements may be made beyond one year. Neurological recovery following moderate/severe TBI is greatest in the first 12 months post-injury, but may occur for up to two years post-injury, with further functional improvements beyond two years. The Division recognizes that 3%–10% of all industrially injured individuals will not recover within the timelines outlined in this document despite optimal care. Such individuals may require treatment beyond the limits discussed within this document, but such treatment will require clear documentation by the authorized treating practitioner focusing on objective functional gains afforded by further treatment. Moderate/severe TBI may have a prolonged recovery and frequently requires continuing treatment as addressed in the post-maximum medical improvement (MMI) care section.
11. Guideline Recommendations and Inclusion of Medical Evidence. Guideline recommendations are based on available evidence and/or consensus recommendations. When possible, guideline recommendations will note the level of evidence supporting the treatment recommendation. When interpreting medical evidence statements in the guideline, the following apply:
    "Some" means the recommendation considered at least one adequate scientific study, which reported that a treatment was effective.

    "Good" means the recommendation considered the availability of multiple adequate scientific studies or at least one relevant high-quality scientific study, which reported that a treatment was effective.

    "Strong" means the recommendation considered the availability of multiple relevant and high quality scientific studies, which arrived at similar conclusions about the effectiveness of a treatment.

    Consensus means the opinion of experienced professionals based on general medical principles. Consensus recommendations are designated in the guideline as "generally well-accepted," "generally accepted," "acceptable," or "well-established."

    There is limited and varied literature on TBI. Therefore, many of the studies cited focus on athletes, the military or treatment for strokes.

    All recommendations in this guideline are considered to represent reasonable care in appropriately selected cases, regardless of the level of evidence attached to them. Those procedures considered inappropriate, unreasonable, or unnecessary are designated in the guideline as "not recommended."

    The remainder of this document should be interpreted within the parameters of this guideline principles that may lead to more optimal medical and functional outcomes for injured workers.

12. Post Maximum Medical Improvement (MMI) Care. This document includes recommendations for post-MMI care in appropriate cases. (Refer to Section M., "Maintenance Management" in the original guideline document.)

Implementation Tools

Clinical Algorithm

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report

Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Colorado Division of Workers' Compensation. Traumatic brain injury medical treatment guidelines. Denver (CO): Colorado Division of Workers' Compensation; 2012 Nov 26. 119 p.

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2012 Nov 26

Guideline Developer(s)

Colorado Division of Workers' Compensation - State/Local Government Agency [U.S.]

Source(s) of Funding

Colorado Division of Workers' Compensation

Guideline Committee

Not stated

Composition of Group That Authored the Guideline

Not stated

Financial Disclosures/Conflicts of Interest

Financial disclosures are on file.

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available from the Colorado Division of Workers' Compensation Web site .

Availability of Companion Documents

The following are available:

- Traumatic brain injury medical treatment guidelines. Bibliography. Denver (CO): Colorado Division of Workers' Compensation; 2012. 42 p. Electronic copies: Available from the Colorado Division of Workers' Compensation Web site .
- Traumatic brain injury medical treatment guidelines. Search terms. Denver (CO): Colorado Division of Workers' Compensation; 2012. 2 p. Electronic copies: Available from the Colorado Division of Workers' Compensation Web site .

In addition, related critiques are available from the Colorado Division of Workers' Compensation Web site . Assessment criteria for critiques are also available from the Colorado Division of Workers' Compensation Web site .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on April 24, 2013. The information was verified by the guideline developer on May 24, 2013. This summary was updated by ECRI Institute on March 10, 2014 following the U.S. Food and Drug Administration advisory on Low Molecular Weight Heparins. This summary was updated by ECRI Institute on April 7, 2014 following the U.S. Food and Drug Administration advisory on Methylphenidate ADHD Medications. This summary was updated by ECRI Institute on September 18, 2015 following the U.S. Food and Drug Administration advisory on non-aspirin nonsteroidal anti-inflammatory drugs (NSAIDs). This summary was updated by ECRI Institute on May 24, 2016 following the U.S. Food and Drug Administration advisory on Olanzapine. This summary was updated by ECRI Institute on June 2, 2016 following the U.S. Food and Drug Administration advisory on Opioid pain medicines. This summary was updated by ECRI Institute on October 21, 2016 following the U.S. Food and Drug Administration advisory on opioid pain and cough medicines combined with benzodiazepines. This summary was updated by ECRI Institute on February 15, 2017 following the U.S. Food and Drug Administration advisory on general anesthetic and sedation drugs.

Copyright Statement

Disclaimer

NGC Disclaimer

The National Guideline Clearinghouseâ„¢ (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional

associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria.

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.